JUL 2 0 2007

K071147

510(k) Summary
for
Nexa Orthopedics Total Shoulder System

1. SPONSOR

Nexa Orthopedics, Inc.
285 West Side Avenue
Suite 251
Jersey City, NJ 07305

Contact Person: Peter Verrillo
Telephone: 201-377-9129

Date Prepared: April 04, 2007

2. DEVICE NAME

Proprietary Name:	Nexa Orthopedics Total Shoulder System
Common/Usual Name:	Total Shoulder Replacement
Classification Name:	Shoulder joint metal/polymer non-constrained cemented prosthesis;
	Shoulder joint metal/polymer semi-constrained cemented prosthesis;
	Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis.

3. PREDICATE DEVICES

- Biomet Bio-Modular Shoulder System (K992119, K992899, K030710, K032507)
- Tornier Aequalis Shoulder System (K063081)
- Axiom Orthopaedics Shoulder Resurfacing System (K061862)

4. DEVICE DESCRIPTION

The Nexa Orthopedics Total shoulder system is comprised of a line of humeral stems, humeral heads, and all polyethylene glenoid components. The humeral stems are sized and shaped to provide proximal fixation and optimal fixation area. Their variable length and proximally filling shape, are designed to accommodate the natural humeral geometry and provide stable fixation, proximal bone loading, and proper head placement with 0 to 3 mm of head adjustment possible. The humeral heads are offered with both spherical and non-spherical articulating surfaces and allow both neutral and offset head positioning via offset taper. The humeral head may articulate against the natural glenoid bone, if it is of sufficient quality, or against the Nexa all polyethylene, cemented glenoid. The glenoid has two or three pegs, depending on size, and is designed to function with both the spherical and non-spherical heads of the Nexa system.

5. INTENDED USE

The Nexa Orthopedics Total Shoulder System consists of a humeral stem, a mating humeral head, and an optional glenoid component. The stem and head may be used by themselves, as a hemiarthroplasty, if the natural glenoid provides a sufficient bearing surface, or in conjunction with the glenoid, as a total replacement. The Nexa Total Shoulder System is to be used only in patients with an intact or reconstructable rotator cuff where it will provide increased mobility and stability as well as reduced pain.

The Nexa Orthopedics Total Shoulder System is indicated for use as a replacement of shoulder joints disabled by the following:

- Rheumatoid arthritis with pain
- Non-inflammatory degenerative joint disease (i.e. osteoarthritis and avascular necrosis)
- Correction of functional deformity
- Fractures of the humeral head
- Traumatic arthritis
- Revision of other devices if sufficient bone stock remains

All components are single use. The humeral stem is intended for cemented or cementless use, while the glenoid is intended for cemented use only.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The proposed Nexa Total Shoulder System and the predicate devices are equivalent in that they all consist of humeral stems, humeral heads, and optional all polyethylene glenoid components. The proposed humeral stems, humeral heads, and glenoid components are equivalent to their predicates in that they are composed of Ti_6Al_4V, CoCrMo, and Ultra High Molecular Weight Polyethylene respectively.

Similarly, both the proposed products and their predicate devices have been designed to mimic the normal humeral canal, humeral head, or glenoid sizing and shape appropriately. Therefore, both the proposed and predicate devices are available in a variety of stem, head, and glenoid sizes.

Furthermore, as with their predicates, the Nexa humeral stem may be press fit, or cemented, while the glenoid is for cemented use only.

7. PERFORMANCE TESTING

The Nexa Orthopedics Total Shoulder System components have been evaluated with respect to the following standards:

- ASTM F2009-00 Standard Test Method for Determining the Axial Disassembly Force of Taper Connections of Modular Prostheses
- ASTM F2028-02 Standard Test Methods for Dynamic Evaluation of Glenoid Loosening or Disassociation.
- ASTM F1378 – 05 Standard for Shoulder Implants
- ASTM 1044 – 05 Standard Test Method for Shear testing of Calcium Phosphate Coatings and Metal Coatings
- ASTM F-1537-00 Standard Specification for Wrought Cobalt-28-Chromium-6-Molybdenum Alloy for Surgical Implants
- ASTM F1147 – 05 Standard Test Method for Tension Testing of Calcium Phosphate and Metallic Coatings
- ASTM F 136 REV A Standard Specification for Wrought Titanium - 6Aluminum - 4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications
- ASTM F648-04 Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 20 2007

Nexa Orthopedics, Inc
% Ms. Mary McNamara-Cullinane
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, MA 02760

Re: K071147
Trade/Device Name: Nexa Orthopedics Total Shoulder System
Regulation Number: 21 CFR 888.3650
Regulation Name: Shoulder joint metal/polymer non-constrained cemented prosthesis
Regulatory Class: II
Product Code: KWT, HSD
Dated: April 4, 2007
Received: April 24, 2007

Dear Ms. McNamara-Cullinane:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Nexa Orthopedics Total Shoulder System

Indications for Use:

The Nexa Orthopedics Total Shoulder System consists of a humeral stem, a mating humeral head, and an optional all polyethylene glenoid. The stem and head may be used by themselves, as a hemiarthroplasty, if the natural glenoid provides a sufficient bearing surface, or in conjunction with the glenoid, as a total replacement shoulder system. The Nexa Total Shoulder System is to be used only in patients with an intact or reconstructable rotator cuff, where it is intended to provide increased mobility and stability and to relieve pain.

The Nexa Orthopedics Total Shoulder System is indicated for use as a replacement of shoulder joints disabled by the following:

- Rheumatoid arthritis with pain
- Non-inflammatory degenerative joint disease (i.e. osteoarthritis and avascular necrosis)
- Correction of functional deformity
- Fractures of the humeral head
- Traumatic arthritis
- Revision of other devices if sufficient bone stock remains

All components are single use. The humeral stem is intended for cemented or cementless use while the all polyethylene glenoid is intended for cemented use only.

Prescription Use ___X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buehler for MXM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071147